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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,251	02/24/2004	Stanley W. Olson JR.	02-125 (US02)	2722

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EXAMINER	
CUMBERLEDGE, JERRY L	
ART UNIT	PAPER NUMBER
3733	

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12/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,251	OLSON ET AL.	
	Examiner	Art Unit	
	Jerry Cumberledge	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-60 and 64-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-60 and 64-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 48-54, 56-58, 60, 64, 65, and 66 are rejected under 35 U.S.C. 102(e) as being anticipated by Margulies et al. (US Pat. 6,679,890 B2).

Margulies et al. disclose a method for delivering implant material into body tissue using a cannula and plunger assembly (Fig. 1), the cannula comprising a cannula body (Fig. 1, ref. 30) having a first longitudinal opening (Fig. 1, ref. 15) and a second transverse opening (Fig. 1, ref. 11) proximal to the first longitudinal opening, the plunger slidably disposed within a lumen of the cannula body (Fig. 1) and having an attached sealing member disposed at a distal end (Fig. 1, ref. 40)(column 4, lines 52-58), the method comprising: inserting the cannula body into targeted body tissue (Fig. 1); perfusing implant material out of the first longitudinal opening into the tissue while the sealing member is in a first position relative to the cannula body and distal to the first longitudinal opening and distal with respect to the cannula body (column 5, lines 40-61); moving the sealing member from the first position to a second position relative to the cannula body, the second position being located within the cannula body and proximal with respect to the first longitudinal opening and distal with respect to the second

transverse opening; and perfusing implant material out of the second transverse opening into the tissue while the sealing member is in the second position (column 5, lines 40-61), wherein implant material is substantially prevented from exiting the cannula body via the first longitudinal opening (column 5, lines 40-61). Separating the distal portion from the proximal portion of the cannula comprises severing the distal portion from the proximal portion via a notch disposed in the cannula body (Fig. 3a)(column 5, lines 64-67). The method further comprises separating a distal portion from a proximal portion of the cannula body after the implant material is perfused out of the respective first longitudinal and second transverse openings (Fig. 3a)(column 5, lines 64-67). The implant material is longitudinally perfused out of the cannula body through the first longitudinal opening, and transversely perfused out of the cannula body through the second transverse opening (Fig. 1). The cannula body further comprises a third transverse opening (Fig. 1, refs. 11) proximal to the second transverse opening, the method further comprising: moving the sealing member from the second position to a third position relative to the cannula body, the third position being located within the cannula body and proximal with respect to the second transverse opening and distal with respect to the third transverse opening; and perfusing implant material out of the third transverse opening into the tissue while the sealing member is in the third position (column 5, lines 40-61). The implant material is bone cement (column 5, lines 31-50). The tissue is bone tissue (Fig. 1).

Margulies et al. disclose a method for delivering implant material into body tissue using a cannula, the cannula comprising a cannula body having a proximal end (Fig. 1),

a distal end (Fig. 1), and one or more openings (Fig. 1, refs. 15 and 11), the method comprising: inserting the cannula body into body tissue (Fig. 1), the cannula body including a plurality of notches (Fig. 3a) disposed in the wall of the cannula body (Fig. 3a); perfusing the implant material out of the one or more openings into the tissue (column 5, lines 40-61); and separating the proximal end from the distal end of the cannula body at one of the plurality of notches (column 5, lines 64-67). The one or more openings comprises a plurality of openings axially spaced from each other along the cannula body the method further comprising perfusing the implant material out of the plurality of openings into the tissue (column 5, lines 40-61). The method further comprises implanting the distal end of the cannula body within the tissue (Fig. 1). The distal end of the cannula body is composed of a biocompatible material (column 6, lines 37-47).

Margulies et al. disclose a method for delivering implant material into body tissue using a cannula and plunger assembly (Fig. 1), the cannula comprising a cannula body (Fig. 1, ref. 20) having a distal end opening (Fig. 1, ref. 15) and a wall opening (Fig. 1, ref. 11) proximal to the distal end opening (Fig, 1), the plunger slidably disposed within a lumen of the cannula body (Fig. 1) (column 5, lines 40-61) and having an attached sealing member (Fig. 1, ref. 9), the method comprising: inserting the cannula body into targeted body tissue (Fig. 1); perfusing implant material out of the distal end opening into the tissue while the sealing member is in a first position relative to the cannula body and distal to the distal end opening (column 5, lines 40-61); moving the sealing member from the first position to a second position relative to the cannula body located within the

cannula body lumen between the distal end opening and the wall opening (column 5, lines 40-61); and perfusing implant material out of the wall opening into the tissue while the sealing member is in the second position (column 5, lines 40-61), wherein implant material is substantially prevented from passing the sealing member and exiting the cannula body via the distal end opening (column 5, lines 40-61).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 55 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margulies et al. (US Pat. 6,679,890 B2) in view of Reiley et al. (US Pat. 6,248,110 B1).

Margulies et al. disclose the claimed method except for the bone tissue being a vertebral body.

Reiley et al. disclose a method for delivering implant material into tissue using a cannula (column 1, lines 53-65), where the tissue can be either a vertebral body (Fig. 39D) or other bones of the body (column 6, lines 3-8) and the method is used to treat fractures or other conditions of bone systems (column 1, lines 35-38).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have used the method of delivering implant material into

tissue using a cannula of Margulies et al. in the vertebra as taught by Reiley et al., in order to treat fractures or other conditions of bone systems (column 1, lines 35-38).

Claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margulies et al. (US Pat. 6,679,890 B2) in view of Scribner et al. (US Pat. 6,241,734 B1).

Margulies et al. disclose the claimed method except for the method further comprises separating a distal portion from a proximal portion of the cannula body after the implant material is perfused out of the respective distal end and wall openings, the separation effectuated by unscrewing the distal portion from the proximal portion via a threaded junction (e.g. a connective sleeve) disposed on the cannula body. Margulies et al. do disclose that the distal end of the cannula can be shortened by trimming it (column 5, lines 64-67).

Scribner disclose connecting a proximal and a distal portion of a cannula that is used in delivery of a surgical material (column 10, lines 45-51)(column 10, lines 40-44), the connection comprising a threaded connector (e.g. a connector sleeve) (column 10, lines 45-51). This connection would allow one to shorten the cannula device through unscrewing the threaded connection on the distal end (Fig. 25) (column 10, lines 45-51)(column 10, lines 40-44).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the trimming step of Margulies et al. with a

step of utilizing a threaded connection as taught by Scribner, in order to achieve the predictable result of shortening the device.

Response to Arguments

Applicant's arguments filed 10/18/2007 have been fully considered but they are not persuasive.

With regard to Applicant's argument that there is no sealing member, ref. 40 of Fig. 1 can be considered to be the sealing member.

With regard to Applicant's argument that the material would be allowed to exit through the longitudinal opening, it is noted by the examiner that the claim states that implant material is substantially prevented from exiting the cannula body via the first longitudinal opening. This occurs when one uses the device of Margulies et al. As cement is placed into the distal end of the cannula (column 5, lines 40-61), the cement will perfuse through the holes of the cannula and into the surrounding tissue where it will fill the surrounding area. The device is then pulled in a proximal direction (column 5, lines 40-61) in order to fill the proximal portions with cement. Since the device is initially placed in the distal portion of the cannula, this portion will be filled first and once cement is place there the remaining cement will be substantially prevented from exiting the longitudinal hole at the distal end. This would happen with the distal holes of the device also. Since they are already filled with bone cement, as the plunger is moved in a proximal direction, the bone cement would be substantially prevented from exiting these holes.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER